Case 3:09-cv-02482-P Document 1 Filed 12/31/09

ORIGINAL

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Dallas Division

Page 1 of 25 distance Dollar Northern district of Texas FILED

DEC 3 | 2009

CLERK, U.S. DISTRICT COURT

By Deputy

UNITED STATES OF AMERICA EX REL. PHI-NGA JEANNIE LE.

Plaintiff,

V.

HBO2WORKS, LLC, HBO2WORKS HOUSTON, LLC, HBO2WORKS SAN ANTONIO, LLC, CROSS HYPERBARIC OF TEXAS, P.L.L.C., STANLEY THAW, MICHAEL KINCAID and PHYLOGIC HEALTHCARE, LLC,

Defendants.

Civil Action No. 3:09cV 2482-K

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b) SEALED

JURY TRIAL DEMANDED

3-09CV2482-K

COMPLAINT

On behalf of the United States of America, plaintiff and relator Phi-Nga Jeannie Le files this *qui tam* complaint against defendants HBO2Works, LLC, HBO2Works Houston, LLC, HBO2Works San Antonio, LLC, Cross Hyperbaric of Texas, P.L.L.C., Stanley Thaw, Michael Kincaid, and PhyLogic Healthcare, LLC and alleges as follows:

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false or fraudulent claims and statements made or caused to be made by defendants to the United States in violation of the False Claims Act, 31 U.S.C. §§ 3729, et seq. ("FCA"). The false or fraudulent claims, statements and records at issue involve payments made by a government-funded health insurance program, Medicare, for services provided by defendants HBO2Works, LLC, HBO2Works Houston,

LLC, HBO2Works San Antonio, LLC, Cross Hyperbaric of Texas, P.L.L.C., Stanley Thaw ("Thaw"), Michael Kincaid ("Kincaid") and PhyLogic Healthcare, LLC ("PhyLogic"). Defendants began submitting fraudulent claims in 2004 and in the ensuing years expanded their continuing fraud.

- 2. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act and in 2009 by the Fraud Enforcement and Recovery Act, 111 P.L. 21, 123 Stat. 1617 (May 20, 2009). The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States. The most recent amendments were intended to "clarify" certain provisions of the False Claims Act "to reflect the original intent of the law," and improve the Federal Government's anti-fraud enforcement efforts. See S. 386 (111th Congress) (2009) (enacted); Senate Report 111-10, Part III, Sec. 4.
- 3. The FCA provides that any person who knowingly submits or causes to submit to the Government a false or fraudulent claim for payment or approval is liable for a civil penalty of between \$5,500 and \$11,000 for each such claim, plus three times the amount of damages sustained by the Government. The Act empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in the recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.
- 4. Pursuant to the FCA, relator seeks to recover on behalf of the United States damages and civil penalties arising from false and fraudulent claims supported by false

statements that defendants submitted or caused to be submitted to a government-funded health insurance program.

PARTIES

- 5. In July 2008, relator Phi-Nga Jeannie Le, M.D., was named Medical Director of defendant HBO2Works Houston, LLC, a provider of hyperbaric oxygen therapy. Dr. Le treated patients at HBO2Works Houston, LLC from October 2008 until December 16, 2008 when she resigned. Dr. Le brings this action for violations of the FCA on behalf of herself and the United States pursuant to 31 U.S.C. § 3730(b)(1).
- 6. Defendants HBO2Works, LLC, HBO2Works Houston, LLC, and HBO2Works San Antonio, LLC provide outpatient hyperbaric oxygen therapy to promote healing in select patients with wounds and injuries. HBO2Works, LLC incorporated in 2004. The company initially opened a facility in Denton, Texas and then moved to Hurst, Texas. In September 2008, HBO2Works Houston, LLC, opened its offices on the premises of Foundation Surgical Hospital and began patient treatment in October 2008. The San Antonio center, HBO2Works San Antonio, LLC, was established in April 2009 and began treating patients in June 2009. A significant percentage of the patients treated at the centers are insured by Medicare.
- 7. Defendants Stanley Thaw and Michael Kincaid, along with Warren Cross, M.D., are the founders and co-owners of defendants HBO2Works, LLC, HBO2Works Houston, LLC, and HBO2Works San Antonio, LLC. Defendant Thaw, a chiropractor, is the President of the three centers and an 80% owner. Defendant Kincaid is the COO of the three centers and a 15% owner. During Dr. Le's time working for the defendants, Thaw and Kincaid directly supervised the day-to-day operations at the Houston and Hurst

centers. Upon information and belief resulting from her prior interactions with defendants, Dr. Le alleges that Thaw and Kincaid also now supervise the daily operations at the San Antonio center. Prior to establishment of the San Antonio center in 2009, Thaw and Kincaid were physically present on alternating weeks at the Hurst and Houston centers. They were present at the centers virtually every day, reviewed patient referral forms and supervised the coding for the submission of the fraudulent claims that are the basis for this suit. Thaw did marketing with the two marketers assigned to each center. Thaw and Kincaid tracked submitted claims and insurance reimbursements on a daily basis.

- 8. PhyLogic Healthcare, LLC, is a privately held company headquartered in Springfield, Massachusetts. The company has provided medical billing and revenue management services to medical practices nationally for the past twelve years. Defendants contracted with PhyLogic to perform billing services for the three HBO2Works centers. Upon information and belief, pursuant to the parties' agreement, PhyLogic reviews the claims data submitted by Defendants, prepares Defendants' claims and submits them to Medicare. Certified coders on staff at PhyLogic provide coding guidance to Defendants. As billing specialists, PhyLogic was required to follow Medicare regulations regarding coding and billing for hyperbaric therapy. It failed to do so and, instead, knowingly and unlawfully conspired with Defendants to submit false claims to Medicare. Upon information and belief, PhyLogic received a percentage of the revenue it collected for Defendants, thereby increasing its own revenues by submitting these fraudulent claims.
- 9. Cross Hyperbaric of Texas, P.L.L.C. ("Cross Hyperbaric"), established in April 2008, is the physician group that billed for the professional services provided at the Houston center. The physician group is named for Warren Cross, a Houston

ophthalmologist, and 5% owner of the three centers. Dr. Cross was not active in the day-to-day operation of the centers. Cross Hyperbaric was established solely to comply with Texas' corporate practice of medicine doctrine, which prohibits physicians from entering into certain financial arrangements with non-physicians. Because physicians may enter into independent contractor arrangements with non-physicians, Cross Hyperbarics serves as a "dummy corporation" to provide contract physicians to HBO2Works Houston, LLC. There is no physician group separate from the physicians working for the HBO2Works Houston, and the registered office of Cross Hyperbaric is Stanley Thaw's home in Plano, Texas. Separate physician groups were also formed for the Hurst and San Antonio centers.

SUMMARY OF ALLEGATIONS

- 10. In connection with their performance of hyperbaric oxygen therapy ("HBOT") for various patients, defendants routinely submitted false claims to Medicare beginning at least five years ago and continuing to the present using five schemes.
- a. **Double Billing for Therapy Sessions.** Defendants submitted fraudulent claims for physician services for two HBOT sessions per day when only one session was provided. A session includes the physician work involved in readying, supervising and attending to the patient during a single HBOT session, regardless of its duration.
- b. **Billing for E&M Services That Were Not Rendered.** The defendants routinely submitted same-day claims for an evaluation and management ("E&M") service in addition to the claim for physician attendance of the HBOT session. A same-day E&M claim may be made only for a separately identifiable service which is unrelated to the

preparation and supervision of the HBOT. No separately identifiable services were provided.

- c. **Upcoding Diagnostic Studies.** Defendants fraudulently submitted claims for physiologic studies which were not performed. Dr. Le routinely performed single level pulse volume recording studies on patients. In order to increase reimbursement, the defendants fraudulently billed for multilevel studies which were not performed.
- d. Falsely Submitting Claims Under a Wrong NPI Number. Dr. Le was the only physician providing hyperbaric therapy to patients at HBO2Works Houston, LLC. Without her knowledge, claims for all Houston patients were submitted falsely to Medicare using the National Provider Identifier ("NPI") number of Dr. John Paul Thompson, the medical director of the Hurst facility, HBO2Works, LLC, despite the fact that he had never seen the patients.
- e. **Billing for Medically Unnecessary Services.** The defendants routinely treated patients whose conditions did not warrant HBOT and/or did not qualify for Medicare reimbursement. Medicare limits reimbursement for HBOT to certain covered conditions. See Medicare Claims Processing Manual, Publication #100-03 Chapter 1, 20.29. In violation of Medicare regulations, the defendants routinely billed for services provided to patients whose conditions did not meet Medicare criteria for a covered condition.

JURISDICTION AND VENUE

11. The Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730.

- 12. The Court has personal jurisdiction over defendants pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and defendants have sufficient minimum contacts with the United States.
- 13. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because the defendants can be found, reside or have transacted business in the Northern District of Texas.
- 14. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit, or investigation or in a Government Accountability Office or Auditor General's report, hearing, audit, investigation, or from the news media.
- 15. To the extent that there has been a public disclosure unknown to the relator, the relator is an original source under 31 U.S.C. § 3730(e)(4). Relator has direct and independent knowledge of the information on which the allegations are based and voluntarily provided the information to the Government before filing this *qui tam* action based on that information. See 31 U.S.C. § 3730(e)(4).

ALLEGATIONS

Government-funded Health Insurance Programs and Hyperbaric Oxygen Therapy

- 16. Medicare is a federally-funded health insurance program primarily benefitting the elderly. It was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare is administered by and through the Centers for Medicare & Medicaid Services ("CMS").
- 17. Hyperbaric oxygen therapy, also known as hyperbaric medicine, is the medical use of 100% oxygen at a pressure that is higher than atmospheric pressure.

Exposing patients to a 100% oxygenated environment at increased pressure significantly increases the oxygen tension of tissues. HBOT is primary in treating certain conditions ranging from gas gangrene to carbon monoxide poisoning to decompression sickness. However, most HBOT, including that administered by defendants, is used as adjunctive treatment to enhance the healing of selected problem wounds, skin grafts and flaps, and delayed radiation injuries. Because of its origins in treating decompression sickness in undersea divers, an HBOT session may be referred to as a "dive."

- 18. HBOT is delivered to patients using either a monoplace chamber which is a single-patient hard-shelled pressure vessel, or larger "multiplace" chambers that accommodate multiple patients and allow medical staff to enter the chamber. The defendants' three centers have "multiplace" chambers which allows for treatment of 8-14 patients simultaneously. In a multiplace chamber, patients breathe oxygen using "oxygen hoods" or tightly fitting aviator-style oxygen masks, which supply 100% oxygen and remove the exhaled gas from the chamber.
- 19. Medicare provides coverage for HBOT only when used to treat a limited number of conditions. These conditions include:
 - a. Acute carbon monoxide intoxication,
 - b. Decompression illness,
 - c. Gas embolism,
 - d. Gas gangrene,
 - e. Acute traumatic peripheral ischemia. HBOT is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened,
 - f. Crush injuries and suturing of severed limbs. As in the previous

- conditions, HBOT would be an adjunctive treatment when loss of function, limb, or life is threatened,
- g. Progressive necrotizing infections (necrotizing fasciitis),
- h. Acute peripheral arterial insufficiency,
- I. Preparation and preservation of compromised skin grafts (not for primary management of wounds),
- j. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
- k. Osteoradionecrosis as an adjunct to conventional treatment,
- I. Soft tissue radionecrosis as an adjunct to conventional treatment,
- m. Cyanide poisoning,
- n. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment, and
- o. Diabetic wounds of the lower extremities in patients who meet the following three criteria: the patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; the patient has a wound classified as Wagner grade III or higher; and patient has failed an adequate course of standard wound therapy.
- 20. Medicare will not reimburse a provider for HBOT provided to treat a condition other than those specified above. See Medicare Claims Processing Manual, Publication #100-04 Chapter 32, 30.1.
- 21. HBOT is classified and reported using the Healthcare Common Procedure Coding System ("HCPCS"), which simplifies the reporting of services rendered and identifies the services or supplies provided. Physician services for HBOT are reported using Level I codes found in Current Procedural Terminology ("CPT"), published by the American Medical Association. The CPT uses five-digit codes with descriptive terms to identify services performed by health care providers and is the country's most widely-

accepted coding reference. The technical component for HBOT is reported using Level II codes designed by CMS. Diagnoses are classified and reported using International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") system, established by CMS and the National Center for Health Statistics. Defendants recorded the CPT and ICD-9 codes that were used for billing on Doctor Charge Sheets prepared for each patient.

- 22. An HBOT provider is permitted to bill for both the technical and professional components of the service. The technical component covers the use of the HBOT chamber and is reimbursed under code C1300, which covers one HBOT dive lasting 45 minutes or less. See Medicare Claims Processing Manual, Publication #100-04 Chapter 32, 30.1. If an HBOT dive lasts between 46-75 minutes, the provider may bill for two units of C1300. Three units of C1300 are billed for HBOT dives of between 76-105 minutes and four units for sessions lasting 106-135 minutes. *Id.*
- 23. Medicare also covers the professional component of a HBOT dive, which includes payment to the physician for attendance at and supervision of the treatment. The physician's work includes readying the patient for the dive, the supervision and attendance during the dive, and the immediate and related routine post-dive work. CPT code 99183 provides for physician billing for this service, which is not time-based. As a result, the professional component is billed per HBOT session, regardless of how long the treatment takes. In summary, one session consists of compression, "bottom time," and decompression.
- 24. The providing physician's NPI number must be on the claim form. See Medicare Claims Processing Manual, Publication #100-04 Chapter 1, 30.2.13. The NPI is

a unique identifier for each healthcare provider that was prescribed by HIPAA. Even if a provider moves, changes specialty, or changes practices, the provider will retain the same NPI but must notify CMS and supply the new information. The provider must correctly identify itself when submitting a claim.

Dr. Le Learns of the Defendants' Fraud

- 25. Dr. Le was an emergency room physician at Foundation Surgical Hospital in February 2008. She was contacted by Dr. Cross regarding the position of Medical Director for HBO2Works Houston, LLC, which was to be opened later in 2008. Dr. Le accepted the position of Medical Director in April 2008. During July 2008, she underwent a forty-hour clinical HBOT training session in San Antonio and also received clinical training on-site at the Hurst facility. She did not receive any training on coding or billing for HBOT.
- 26. HBO2Works Houston, LLC's hyperbaric chamber arrived at Foundation Surgical Hospital in September 2008, and Dr. Le evaluated the first patient for HBOT later that month. Over the next two months Dr. Le was repeatedly instructed to engage in multiple fraudulent billing schemes. Although Dr. Le had no training in coding for HBOT, within two months of seeing her first patient, Dr. Le discovered the defendants' fraud.
- 27. When Dr. Le challenged the defendants about their wrongdoing, they assured her the billing was proper, and they persisted in their practices. Unable to change these practices, Dr. Le contacted the Office of the Inspector General and the Federal Bureau of Investigation on November 28, 2008. She resigned as Medical Director on December 16, 2008.
- 28. Dr. Le sent resignation letters regarding the billing fraud and unethical medical practices to Thaw, Kincaid, Cross and Lee V. Ansell, M.D., the Chief of the Medical

Staff at Foundation Surgical Hospital in Houston, Texas. Dr. Ansell contacted Dr. Le and asked her if the defendants were defrauding Medicare. Dr. Le stated that they were. Ansell then met with Thaw and Cross regarding the allegations, and they assured him the billing was appropriate and they would have a consultant review their practices if necessary.

Defendants' Primary Fraud: Double Billing for Therapy Sessions

- 29. Beginning with the opening of HBO2Works, LLC, in 2004, HBO2Works Houston, LLC, in 2008, and HBO2Works San Antonio, LLC, in 2009, and upon information and belief, continuing to the present, the defendants submitted false claims for physician services for two sessions of HBOT when only one session was provided.
- 30. For most problem wounds, HBOT is prescribed 5-6 days per week for 20-40 treatments, with each daily treatment lasting 120-150 minutes. Occasionally, some patients may require additional treatments. Each session includes preparation and placement of the patient in the HBO pressurized chamber during which time the patient breathes 100% oxygen. The session may include 5-10 minute air breaks, during which time the patient is off 100% oxygen, and decompression of the patient for removal from the chamber. Only for certain emergent or urgent conditions is more than one HBO session per day medically reasonable and necessary.
- 31. CPT code 99183 provides for physician attendance and supervision of HBOT on a per session basis. See Medicare Claims Processing Manual, Publication #100-04 Chapter 32, 30.1. CPT code 99183 is not a time-based code and, therefore, may be submitted only once per session regardless of the session's length.
 - 32. Dr. Le completed Doctor Charge Sheets for each patient's initial evaluation

and subsequent HBOT session. The Doctor Charge Sheet lists HBOT related CPT codes and their descriptions. CPT code 99183 is listed twice on this sheet. The first listing for this code is followed by a description: "hyperbaric oxygen therapy." The second listing of CPT code 99183 is followed by a different description: "Physician attendance & supervision of HBO, per session."

- 33. Dr. Le understood that CPT code 99183 was to be submitted once per session, and she routinely circled the code once. Dr. Le asked Dr. Thompson why CPT code 99183 was listed twice with different descriptors. Dr. Thompson stated this was an error that was never corrected, and Dr. Le should pick one. After completing the Doctor Charge Sheets, Dr. Le placed them in a box at the center's office on the fourth floor of Foundation Surgical Hospital. These sheets were faxed to the billing company, PhyLogic. A summary of the charges was prepared routinely for review by Thaw and Kincaid.
- 34. In October 2008, Kincaid met with Dr. Le at the office in Foundation Surgical Hospital and stated she should sign a blank Doctor Charge Sheet to expedite billing. The signed sheet would be photocopied and a staff member would fill in the CPT codes. Dr. Le refused and indicated she would complete the sheet as she treated each patient.
- 35. Kincaid met with Dr. Le twice in November 2008 regarding the coding on the Doctor Charge Sheets. Kincaid stated that Dr. Le was not consistently submitting CPT code 99183 twice per session, and he instructed Dr. Le to use this code twice per session of HBOT by placing "X 2" beside the CPT code. Kincaid told Dr. Le that CPT code 99183 should be billed twice for two reasons: 1) the Houston chamber was a multiplace chamber and "multiplace chambers are two hours," and 2) "per session is per hour" so HBOT sessions longer than one hour required billing CPT code 99183 twice. Kincaid insisted that

the use of CPT code 99183 twice per session was correct, that Thaw had approved this practice, and it was routinely done at the Hurst facility.

- 36. Dr. Le confronted Kincaid about this practice during the last week in November 2008 shortly before her resignation. Dr. Le asked Kincaid for documentation to support the practice of billing CPT code 99183 twice per session of HBOT. Kincaid stated that this was "how we do it." When Dr. Le persisted, Kincaid stated he would provide the documentation, but the following day Kincaid stated he could not obtain the documentation from PhyLogic because his contact person was out of town.
- 37. For each single HBOT dive, the defendants routinely billed Medicare for physician supervision of two sessions of HBOT using CPT code 99183. PhyLogic specialists reviewed this data. In fact, Rebecca at PhyLogic flagged several Doctor Charge Sheets in a fax to Kincaid on November 24, 2008, noting that on some sheets CPT code 99183 was marked twice and on some it was "marked *only* once." The company states that claims are "scrubbed for errors" and that there are "literally thousands of checks performed" prior to claim submission. See PhyLogic at http://www.phylogic.com/# (last visited Oct. 19, 2009). But PhyLogic did not correct these claims and, instead, submitted the false claims to Medicare for payment.
- 38. The defendants' submission of false claims for physician supervision using CPT code 99183 twice doubled their reimbursement for the professional component of the dive.

Billing for E&M Services that Were Not Rendered

39. The defendants routinely submitted fraudulent same-day claims for an E&M service in addition to the service for physician supervision of the HBOT session. An E&M

service code may not be used on the same day as the HBOT CPT code unless an E&M service which is separately identifiable from the HBOT preparation and supervision is provided.

- 40. CPT code 99183 includes physician preparation of the patient for the HBOT (including, for instance, a short pre-therapy examination and follow-up evaluation of the wound being treated), supervision during treatment and breaks, and decompression at the termination of the session. Drs. Le and Thompson provided the required physician preparation and supervision encompassed in CPT code 99183. No separate evaluation and management services were provided.
- 41. The Hurst facility routinely submitted an E&M code in addition to CPT code 99183. This was not the case for the Houston facility, and Rebecca at PhyLogic pointed this out to Kincaid. In a fax from Rebecca to Kincaid on November 24, 2008 Rebecca noted that "no office visits selected except for the consult ones." In late November 2008, Kincaid met with Dr. Le. He instructed Dr. Le to submit a claim for an E&M code, 99212 or 99213, in addition to CPT code 99183 twice for each HBOT session, even though no separate E&M service was performed.
- 42. Dr. Le contacted Dr. Thompson, and he confirmed that an E&M code was submitted in addition to the HBOT codes. Although he again acknowledged that he signed blank Doctor Charge Sheets, he said an E&M code should be submitted in addition to the HBOT code, 99183, because two separate services were being provided. The defendants collaborated to submit fraudulently an E&M code in addition to CPT code 99183.

Upcoding of Diagnostic Tests

43. The vast majority of the patients seen at the Hurst and Houston facilities were

treated for single non-healing, lower extremity wounds. Upon initial presentation, all new patients underwent a single-level pulse volume recording ("PVR") study to evaluate their lower extremity arterial blood flow regardless of need.

- 44. A PVR study is a non-invasive vascular test in which blood pressure cuffs and a hand-held ultrasound device (called a Doppler or transducer) are used to obtain information about arterial blood flow in an extremity. This study is used on an outpatient basis if there is a question regarding the patency of large arteries supplying the lower extremity where the wound is located. If a wound is due to chronic ischemia caused by large arterial occlusion HBOT is ineffective unless the patient has multiple small collateral vessels to supply the wound. Usually the patient with large arterial occlusion would require a bypass graft prior to receiving HBOT.
- 45. Two separate CPT codes are used to designate a PVR study: CPT code 93922 designates a single-level study, and CPT code 93923 designates a multilevel study. A single-level study consists of the placement of pressure cuffs on each leg at a level adjacent to the wound. The result from the normal leg is compared to the leg with the wound. A multilevel study includes the single level study, as described above, plus an additional pressure study done at a second level much further away from the wound. Multilevel level studies are indicated in patients with multiple leg wounds at different levels. If there is a significant distance between the wounds, the blood flow near each wound is assessed.
- 46. CPT codes 93922 and 93923 include several different types of noninvasive arterial studies *i.e.* the PVR and transcutaneous oxygen tension measurement ("TCOM"). On the defendants' Doctor Charge Sheets, the PVR studies were designated as "93922".

TCOM, Single level" and "93923 TCOM, Multiple levels."

- 47. Single level studies were routinely performed at defendants' centers. In mid-to-late October 2008, Kincaid and Dr. Le were working in their fourth floor office of HBO2Works Houston, LLC in Foundation Surgical Hospital. Dr. Le had been submitting claims for the single level study. Kincaid told her that she was "undercoding" the PVR study; the single level studies being performed should be coded as a multilevel study because one test was performed on each leg. He noted that the Hurst center routinely submitted claims for multilevel studies. Dr. Le began researching the codes while submitting CPT code 93923 for single level studies. Within 2-3 weeks, she discovered this fraudulent scheme and prepared her resignation.
- 48. A claim for a single level study using CPT code 93922 reimburses approximately \$120.99. Although a multilevel study was not performed, the defendants routinely submitted claims using CPT code 93923 in order to receive the higher reimbursement of approximately \$187.35, resulting in an overpayment by Medicare in excess of 50%.

Treating Patients in Violation of Medicare Regulations

49. The defendants routinely treated patients with HBOT in violation of Medicare regulations. Patients that are candidates for HBOT are seen by a primary care physician who then makes the referral to the HBO center. In early October 2008, Thaw met with Dr. Le and told her that he or Kincaid would review the diagnosis and insurance information for every patient referred. Either Thaw or Kincaid would decide whether the patient would undergo HBOT, although neither Thaw nor Kincaid is a licensed medical doctor. The defendants determined if a patient met Medicare and told Dr. Le that if she felt otherwise,

she had to provide them with a justification.

- 50. In early October, when the Houston center's first patient was referred, Dr. Le had a discussion with the defendants regarding criteria for HBOT. In the fourth floor office at Foundation Surgical Hospital, Thaw and Kincaid stated they reviewed all patient referrals. Thaw said it was a "slam dunk" that all diabetic patients with a lower extremity wound meet Medicare criteria so there should be no question regarding HBOT treatment for these patients. Thaw and Kincaid instructed Dr. Le to treat any diabetic patient with lower extremity wounds although some did not qualify for HBOT under Medicare regulations.
- 51. In order for a diabetic patient to meet criteria for HBOT reimbursement by Medicare, the diabetic wound of the lower extremity must be a Wagner Grade III or higher and the patient must have failed an adequate course of standard wound therapy (*i.e.*, wound debridement and antibiotic treatments). See Medicare Claims Processing Manual, Publication #100-03 Chapter 1, 20.29. At the outset, in October 2008, Thaw and Kincaid told Dr. Le to treat all diabetic wounds regardless of whether they met Medicare criteria. HBOT treatment was provided solely to increase reimbursement although the treatment was not medically indicated.
- 52. For example, Dr. Le was presented with a referral for patient PG¹ in October 2008. Kincaid told Dr. Le that "I need you to make this a failed flap." Medicare covers HBOT to preserve compromised skin grafts. The patient did not have a wound flap or graft,

¹ In order to maintain the privacy and confidentiality of sensitive healthcare information, patients are referred to here by their initials. Relators will identify the patients under an appropriate protective order.

and Dr. Le told Kincaid she would not lie to Medicare and would not make up an improper diagnosis. Dr. Le later discovered the patient had osteomyelitis, a covered condition, and HBOT was appropriately provided.

- 53. Additionally, at the Houston and Hurst facilities, and upon information and belief at the San Antonio facility, patients underwent more HBOT sessions than medically indicated. Many patients received 60-80 HBO sessions, strictly to increase reimbursements, when only 20-30 were medically indicated for non-healing wounds and approximately 40 for delayed radiation injury.
- 54. While Dr. Le was at the Hurst facility in July 2008, she was talking with Kincaid in an office at Southwest Surgical Hospital. Brandy, the supervising technician and acting manager at the Hurst facility, joined Dr. Le and Kincaid. Brandy stated that a particular patient with a wound which was healing well should complete HBOT soon. Kincaid said, "Stop healing him. Can't you stretch this out longer?" Kincaid stated that patients were treated as long as they had a wound and the treatments would extend to 60-80 sessions. Kincaid told Dr. Le that in Hurst treatment would continue as long as the patient had a visible wound, well beyond what was indicated.

Claims Were Submitted Falsely Identifying the Treating Physician

- 55. The defendants falsely submitted claims for Dr. Le's treatment of patients at the Houston facility using Dr. Thompson's NPI number.
- 56. Each physician performing services for a patient must be identified on the claim form by his or her NPI number. See Medicare Claims Processing Manual, Publication #100-04 Chapter 1, 30.2.13. The NPI is a unique identification number for

covered health care providers and must be used on claim form submissions. In violation of Medicare regulations Dr. Le's NPI number was not used. By using the incorrect NPI number, defendants falsely identified Dr. Thompson as the treating physician, when, in fact, the patients were treated by Dr. Le.

57. Thaw and Kincaid used Dr. Thompson's NPI number for services Dr. Le provided at the Houston facility. PhyLogic submitted the claims for HBOT provided by defendants at both the Hurst and Houston facilities. It was aware that two different physicians in separate cities were providing services simultaneously. In spite of this, PhyLogic knowingly submitted the claims for treatment performed by Dr. Le using Dr. Thompson's NPI number.

COUNT ONE False Claims Act 31 U.S.C. §§ 3729(a)(1) (1986) and 3729(a)(1)(A) (2009)

- 58. Relator re-alleges and incorporates by reference the allegations contained in Paragraphs 1 through 57 of this complaint.
- 59. For conduct occurring before the date of enactment of the Fraud Enforcement and Recovery Act of 2009, 111 P.L.21, 123 Stat. 1617 (May 20, 2009), this is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729(a)(1).
- 60. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to the United States Government false or fraudulent claims.
- 61. For conduct occurring on or after the date of enactment of the Fraud Enforcement and Recovery Act of 2009, 111 P.L.21, 123 Stat. 1617 (May 20, 2009), this is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(a).

- 62. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval.
- 63. By virtue of the acts described above, Defendants knowingly concealed the existence of their improper conduct from the United States Government in order to induce payment of false or fraudulent claims.
- 64. The United States, unaware of the Defendants' wrongdoing or the falsity or fraudulent nature of the claims submitted by the Defendants, paid claims that would not otherwise have been allowed.
- 65. By reason of these payments, the United States has been damaged, and continues to be damaged, in substantial amount.

COUNT TWO False Claims Act 31 U.S.C. § 3729(a)(1)(B) (2009)

- 66. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 1 through 57 of this complaint.
- 67. Through the acts described in this Complaint, Defendants knowingly made, used, or caused to be made and used false records and statements, material to false or fraudulent claims.
- 68. The United States, unaware of the Defendants' wrongdoing or the falsity of the records, statements, or false or fraudulent claims made by the Defendants or Defendants' wrongdoing, paid claims that would not otherwise have been allowed.
- 69. By reason of these payments, the United States has been damaged, and continues to be damaged, in substantial amount.

COUNT THREE False Claims Act 31 U.S.C. §§ 3729(a)(3) (1986) and 3729(a)(1)(C) (2009)

- 70. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 1 through 57 of this complaint.
- 71. For conduct occurring before the date of enactment of the Fraud Enforcement and Recovery Act of 2009, 111 P.L.21, 123 Stat. 1617 (May 20, 2009), this is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729(a)(3).
- 72. By virtue of the acts described above, defendants conspired to defraud the United States Government by getting a false or fraudulent claim paid as described above.
- 73. For conduct occurring on or after the date of enactment of the Fraud Enforcement and Recovery Act of 2009, 111 P.L.21, 123 Stat. 1617 (May 20, 2009), this is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(C).
- 74. By virtue of the acts described above, Defendants knowingly conspired to commit a violation of the False Claims Act as described above.
- 75. The United States, unaware of the defendants' conspiracy, paid the defendants for claims that would otherwise not have been allowed.
- 76. By reason of these payments, the United States has been damaged, and possibly continues to be damaged, in a substantial amount.

WHEREFORE, Relator requests that judgment be entered in his favor against Defendants, ordering that:

- a. Defendants cease and desist from violating 31 U.S.C. § 3729;
- b. Defendants pay an amount equal to three times the amount of damages

the United States has sustained as a result of Defendants' actions, plus a civil penalty of \$11,000 for each violation of 31 U.S.C. § 3729;

- c. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);
- d. Defendants pay all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d); and
- e. the United States and Dr. Le receive such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, relator hereby demands a trial by jury.

Respectfully submitted,

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ATTORNEYS IN CHARGE FOR QUI TAM RELATOR PHI-NGA JEANNIE LE

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The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provide the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I () DI AINTENES	INSTRÛCTIONS ON THE REVERSE OF THE FORM.)			- Court for the purpose of initiat
1. (a) FLAINTIFFS	MANDER SEAL)	DEFENDANTS	[UNDER SEAL]	
216	Mileson of Ood	V2482-1		
	e of First Listed Plaintiff			
1 1	EXCEPT IN U.S. PLAINTIFF CASES)	County of Residence	of First Listed Defendant (IN U.S. PLAINTIFF CASES	ONI V)
	,	NOTE: IN LA	ND CONDEMRECENCIOES, U	
		LANI	INVOLEND.	
(c) Attorney's (Firm Nam	ne, Address, and Telephone Number)	Attorneys (If Known)		
Mitch Kreindler	, Kreindler & Associates, 9219 Katy F	wv. Ste	DEC 3 2009	
206, Houston,	TX 77024; 713.647.8888	7,	DEG O 1 moor	
II. BASIS OF JURIS	DICTION (Place an "X" in One Box Only)	III. CITIZENSHIP OF	PR NCIPAL MARKUES	Old in "" in One Box for Plaint
☐ 1 U.S. Government	■ 3 Federal Question	(For Diversity Cases Only)	NORTHERN DISTRICT OF	and One Box for Defendant)
Plaintiff	(U.S. Government Not a Party)	Citizen of This State	☐ 1 Incorporated or Pr	rincipal Place 🔲 4 🗍 4
			of Business In Th	is State
2 U.S. Government Defendant	☐ 4 Diversity	Citizen of Another State	☐ 2 Incorporated and	
	(Indicate Citizenship of Parties in Item III)		of Business In	Another State
		Citizen or Subject of a Foreign Country	□ 3 Foreig Nation	
IV. NATURE OF SU		1 Toroign Country	Vi. /	ALLU
CONTRACT		FORFEITURE/PENALTY	BANKRUPTCY	OTHERSTATUTES
☐ 110 Insurance ☐ 120 Marine	PERSONAL INJURY PERSONAL INJURY 310 Airplane 362 Personal Injury		☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 130 Miller Act	☐ 315 Airplane Product Med. Malpracti		☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust ☐ 430 Banks and Banking
140 Negotiable Instrument	Liability	- of Property 21 USC 881	20 050 137	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgmen			PROPERTY RIGHTS	460 Deportation
☐ 151 Medicare Act	330 Federal Employers' Injury Product	al	☐ 820 Copyrights ☐ 830 Patent	470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted	Liability Liability	☐ 660 Occupational	☐ 840 Trademark	☐ 480 Consumer Credit
Student Loans (Excl. Veterans)	☐ 340 Marine PERSONAL PROPEI ☐ 345 Marine Product ☐ 370 Other Fraud	1		☐ 490 Cable/Sat TV
☐ 153 Recovery of Overpayment	Liability 370 Other Fraud	☐ 690 Other LABOR	SOCIAL SECURITY	■ 810 Selective Service ■ 850 Securities/Commodities/
of Veteran's Benefits 160 Stockholders' Suits	☐ 350 Motor Vehicle ☐ 380 Other Personal	☐ 710 Fair Labor Standards	□ 861 HIA (1395ff)	Exchange
190 Other Contract	☐ 355 Motor Vehicle Property Damag Product Liability ☐ 385 Property Damag		☐ 862 Black Lung (923)	☐ 875 Customer Challenge
☐ 195 Contract Product Liability	☐ 360 Other Personal Product Liability		☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI	12 USC 3410 890 Other Statutory Actions
☐ 196 Franchise REAL PROPERTY	Injury	& Disclosure Act	☐ 865 RSI (405(g))	891 Agricultural Acts
☐ 210 Land Condemnation	CIVIL RIGHTS PRISONER PETITIO ☐ 441 Voting ☐ 510 Motions to Vaca		FEDERAL TAX SUITS	892 Economic Stabilization A
220 Foreclosure	442 Employment Sentence	te 790 Other Labor Litigation 791 Empl. Ret. Inc.	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 893 Environmental Matters ☐ 894 Energy Allocation Act
230 Rent Lease & Ejectment	☐ 443 Housing/ Habeas Corpus:	Security Act	☐ 871 IRS—Third Party	895 Freedom of Information
☐ 240 Torts to Land ☐ 245 Tort Product Liability	Accommodations		26 USC 7609	Act
290 All Other Real Property	 444 Welfare 535 Death Penalty 540 Mandamus & Other 	IMMIGRATION ther ☐ 462 Naturalization Application	n	 900Appeal of Fee Determination Under Equal Access
	Employment	☐ 463 Habeas Corpus -		to Justice
	Other 555 Prison Condition			☐ 950 Constitutionality of
	440 Other Civil Rights	☐ 465 Other Immigration Actions		State Statutes
V. ORIGIN (Place	an "X" in One Box Only)			
▼1 Original □ 2 R	emoved from 3 Remanded from		sferred from 6 Multidistr	Appeal to District 7 Judge from
Proceeding St	ate Court Appellate Court	Reopened anoth	ify) Litigation	
<u> </u>	Cite the U.S. Civil Statute under which you a False Claims Act. 31 U.S.C. sec	re filing (Do not cite jurisdiction	al statutes unless diversity):	
VI. CAUSE OF ACTI	Brief description of cause:	. 3129. Et Seu.		·
	Seeking recovery for false claim	s submitted to the United	States	
VII. REQUESTED IN	CHECK IF THIS IS A CLASS ACTION	N DEMAND \$		if demanded in complaint:
COMPLAINT:	UNDER F.R.C.P. 23		JURY DEMAND:	🗗 Yes 🗆 No
VIII. RELATED CAS	E(S)			
IF ANY	(See instructions): JUDGE		DOCKET NUMBER	
DATE	SIGNATURE OF AT	TORNEY OF RECORD		
12/28/2009	Marke		Mitchell R. Kreindle	er
FOR OFFICE USE ONLY			- Transfer	-
RECEIPT # A	MOUNT APPLYING IFP	ЛUDGE	MAG. JUD	OGE